

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No.:	09/436,347	Group Art Unit:	1643
Confirmation No.:	6491	Examiner:	A.M. Harris
Filed:	9 November 1999		
Inventor:	Christine A. WHITE <i>et al.</i>		
For:	Treatment of Chronic Lymphocytic Leukemia using Anti-CD20 Antibodies (as amended)		

Mail Stop **Amendment**
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

In compliance with the requirements and provisions of 37 C.F.R. §§ 1.56, 1.97, and 1.98, applicant cites the information listed on the Form PTO-1449 that accompanies this paper and the pending patent applications identified below. Applicant does not represent that a search has been conducted or that the cited documents are prior art against the claims in this application.

Copies of the cited non-U.S. patent documents, with the exception of items D62, D101, D153, D204, and D257 accompany this submission. The latter documents were submitted as attachments to the RCE and amendment filed on 7 August 2006 and are not duplicated here.

This disclosure statement is filed under the provisions of 37 C.F.R. § 1.97(b)(4) prior to the mailing date of an action on the merits following a Request for Continued Examination under 37 C.F.R. § 1.114. Applicant believes that no fee is due in connection with this disclosure statement. However, should any additional fee be required to render this paper timely or proper, applicant requests that the Director charge the required fee to our Deposit Account No. 18-1260.

Copending patent applications

In addition to the information cited on the Form PTO-1449 that accompanies this paper, applicant directs the examiner's attention to the commonly-owned pending U.S. patent applications listed below.

Serial No.	Filing Date	First Inventor
09/628,187	28 Jul 2000	White
09/762,587	06 Sep 2001	Grillo-López
09/911,692	25 Jul 2001	Anderson
09/911,703	25 Jul 2001	Anderson
10/096,964	14 Mar 2002	Anderson
10/196,732	17 Jul 2002	Grillo-López
10/238,681	11 Sep 2002	Anderson
10/440,186	19 May 2003	Grillo-López
10/850,712	21 May 2004	Grillo-López

Respectfully submitted,

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INFORMATION DISCLOSURE STATEMENT	Docket No.	27693-01201	Serial No:	09/ 436,347
	Inventor(s):	Christine WHITE <i>et al.</i>	Examiner:	A.M. HARRIS
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U.S. PATENT DOCUMENTS

INITIAL	INDEX	DOCUMENT	DATE	NAME	CLASS	SUB.	FILING DATE
	D1	Re 38,008	25 Feb 2003	Abrams			
	D2	4,831,175	16 May 1989	Gansow			
	D3	4,975,278	4 Dec 1990	Senter			
	D4	5,099,069	24 Mar 1992	Gansow			
	D5	5,124,471	23 Jun 1992	Gansow			
	D6	5,246,692	21 Sep 1993	Gansow			
	D7	5,286,850	15 Feb 1994	Gansow			
	D8	5,439,665	8 Aug 1995	Hansen			
	D9	5,460,785	24 Oct 1995	Rhodes			
	D10	5,595,721	21 Jan 1997	Kaminski			
	D11	5,648,267	15 Jul 1997	Reff			
	D12	5,677,180	14 Oct 1997	Robinson			
	D13	5,686,072	11 Nov 1997	Uhr			
	D14	5,691,320	25 Nov 1997	van Borstel			
	D15	5,693,780	2 Dec 1997	Newman			
	D16	5,721,108	24 Feb 1998	Robinson			
	D17	5,726,023	10 Mar 1998	Cheever			
	D18	5,843,398	1 Dec 1998	Kaminski			
	D19	6,015,542	18 Jan 2000	Kaminski			
	D20	6,090,365	18 Jul 2000	Kaminski			
	D21	6,120,767	19 Sep 2000	Robinson			
	D22	6,287,537 B1	11 Sep 2001	Robinson			

EXAMINER	DATE CONSIDERED
Initial if a citation is considered, whether or not citation is in conformance with MPEP § 609. Draw line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.	
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INITIAL	INDEX	DOCUMENT	DATE	NAME	CLASS	SUB.	FILING DATE
	D23	6,565,827 B1	20 May 2003	Kaminski			
	D24	6,652,852 B1	25 Nov 2003	Robinson			
	D25	6,893,625 B1	17 May 2005	Robinson			
	D26	2002/ 0009444 A1	24 Jan 2002	Grillo-López			
	D27	2002/ 0197255 A1	26 Dec 2002	Anderson			
	D28	2003/ 0021781 A1	30 Jan 2003	Anderson			
	D29	2003/ 0026804 A1	24 Feb 2003	Grillo-López			
	D30	2003/ 0082172 A1	1 May 2003	Anderson			
	D31	2003/ 0095963 A1	22 May 2003	Anderson			
	D32	2003/ 0206903 A1	6 Nov 2003	Grillo-López			
	D33	2004/ 0167319 A1	26 Aug 2004	Teeling			
	D34	2004/ 0213784 A1	28 Oct 2004	Grillo-López			
	D35	2004/ 056312 A2	8 Jul 2004	Adams			
	D36	2005/ 0163708 A1	28 July 2005	Robinson			
	D37	2005/ 0186205 A1	25 Aug 2005	Anderson			
	D38	2006/ 0034835 A1	16 Feb 2006	Adams			

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FOREIGN PATENT DOCUMENTS

INITIAL	INDEX	DOCUMENT	DATE	COUNTRY	CLASS	SUB.	TRANSLATION	
	D39	0 125 023 A1	14 Nov 1994	EP				
	D40	0 173 494 A2	5 May 1986	EP				
	D41	0 274 394 A2	13 Jul 1988	EP				
	D42	0 451 216 B1	24 Jan 1996	EP				
	D43	0 669 836 B1	7 Mar 1996	EP				
	D44	0 682 040 A1	15 Nov 1995	EP				
	D45	0 752 248 A1	8 Jan 1997	EP				
	D46	87/ 02671 A1	7 May 1987	WO				
	D47	88/ 04936 A1	14 Jul 1988	WO				
	D48	89/ 00999 A1	9 Feb 1989	WO				
	D49	91/ 04320 A1	4 Apr 1991	WO				
	D50	92/ 07466 A1	14 May 1992	WO				
	D51	93/ 02108 A1	4 Feb 1993	WO				
	D52	94/11026 A2	26 May 1994	WO				
	D53	00/ 09160 A1	24 Feb 2000	WO				
	D54	00/ 27428 A1	18 May 2000	WO				
	D55	00/ 27433 A1	18 May 2000	WO				
	D56	01/ 10460 A1	15 Feb 2001	WO				
	D57	2004/ 056312 A2	8 Jul 2004	WO				

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OTHER DOCUMENTS

INITIAL	INDEX	CITATION
	D58	Adams R.A. <i>Cancer Res.</i> 27: 2479-82, 1967. Formal discussion: the role of transplantation in the experimental investigation of human leukemia and lymphoma.
	D59	Adams R.A. et al. <i>Cancer Res.</i> 28(6): 1121-25, 1968. Direct implantation and serial transplantation of human acute lymphoblastic leukemia in hamsters, SB-2.
	D60	Alas S. et al. <i>Clin. Cancer Res.</i> 7(3): 709-23, 2001. Inhibition of interleukin 10 by rituximab results in down-regulation of bcl-2 and sensitization of B-cell non-Hodgkin's lymphoma to apoptosis.
	D61	Alas S. et al. <i>Clin. Cancer Res.</i> 8(3): 836-45, 2002. Rituximab modifies the cisplatin-mitochondrial signaling pathway, resulting in apoptosis in cisplatin-resistant non-Hodgkin's lymphoma.
	D62	Almasri N.M. et al. <i>Am. J. Hematol.</i> 40: 259-63, 1992. Reduced expression of CD20 antigen as a characteristic marker for chronic lymphocytic leukemia.
	D63	Anderson D.R. et al. <i>Biochem. Soc. Trans.</i> 25(2): 705-08, 1997. Targeted anti-cancer therapy using rituximab, a chimaeric anti-CD20 antibody (IDEC-C2B8) in the treatment of non-Hodgkin's B-cell lymphoma.
	D64	Anderson D.R. et al. Second IBC Int'l. Conference on Antibody Engineering, San Diego, 16-18 December 1991. Immunoreactivity and effector function associated with a chimeric anti-CD20 antibody (abstract of presentation).
	D65	Anderson K.C. et al. <i>Blood</i> 63(6): 1424-33, 1984. Expression of human B cell-associated antigens on leukemias and lymphomas: a model of human B cell differentiation.
	D66	Anderson K.C. et al. <i>Blood</i> 69(2): 597-604, 1987. Hematologic engraftment and immune reconstitution posttransplantation with anti-B1 purged autologous bone marrow.
	D67	Appelbaum F.R. <i>Hem. Onc. Clin. N. Amer.</i> 5(5): 1013-25, 1991. Radiolabeled monoclonal antibodies in the treatment of non-Hodgkin's lymphoma.
	D68	Armitage J.O. et al. <i>Cancer</i> 50: 1695-1702, 1982. Predicting therapeutic outcome in patients with diffuse histiocytic lymphoma treated with cyclophosphamide, adriamycin, vincristine and prednisone (CHOP).

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INITIAL	INDEX	CITATION
	D69	Armitage J.O. et al. <i>J. Clin. Oncol.</i> 16(8): 2780-95, 1998. New approach to classifying non-Hodgkin's lymphomas: clinical features of the major histologic subtypes. Non-Hodgkin's Lymphoma Classification Project.
	D70	Azogui O. et al. <i>J. Immunol.</i> 131: 1205-08, 1983. Inhibition of IL-2 production after human allogeneic bone marrow transplantation.
	D71	Badger C.C. et al. <i>Cancer Res.</i> 46: 6223-28, 1986. Experimental radioimmunotherapy of murine lymphoma with ¹³¹ I-labeled anti-T-cell antibodies.
	D72	Berinstein N.L. et al. <i>Ann. Oncol.</i> 9: 995-1001, 1998. Association of serum rituximab (IDEC-C2B8) concentration and anti-tumor response in the treatment of recurrent low-grade or follicular non-Hodgkin's lymphoma.
	D73	Beychok S. (in) <i>Cells of Immunoglobulin Synthesis</i> , B. Pernis et al., eds. New York: Academic Press, 1979, 69-88. Comparative aspects of <i>in vitro</i> and cellular assembly of immunoglobulins.
	D74	Bhan A.K. et al. <i>J. Exp. Med.</i> 154: 737-49, 1981. Stages of B cell differentiation in human lymphoid tissue.
	D75	<i>Biogen Idec Inc. v. Corixa Corp.</i> , Case No. 01-CV-1637 IEG (RBB), Order Granting Patentees' Motion for Reconsideration, <i>etc.</i> (S.D.Cal., Jan. 22, 2004).
	D76	<i>Biogen Idec Inc. v. Corixa Corp.</i> , Case No. 01-CV-1637 IEG (RBB), Stipulation of Dismissal of Claims and Counterclaims with Prejudice and Order (S.D.Cal., May 13, 2004).
	D77	Bosly A. et al. <i>Nouv. Rev. Fr. Hematol.</i> 32(1): 13-16, 1990. Interleukin-2 after autologous bone marrow transplantation as consolidative immunotherapy against minimal residual disease.
	D78	Boulianne G.L. et al. <i>Nature</i> 312: 643-46, 1984. Production of functional chimeric mouse/human antibody.
	D79	Brunner K.T. et al. <i>Immunology</i> 14(2): 181-96, 1968. Quantitative assay of the lytic action of immune lymphoid cells on ⁵¹ Cr-labelled allogeneic target cells <i>in vitro</i> ; inhibition by isoantibody and by drugs.
	D80	Buchsbaum D.J. et al. <i>Cancer Res.</i> 50: 993s-999s, 1990. Comparative binding and preclinical localization and therapy studies with radiolabeled human chimeric and murine 17-1A monoclonal antibodies.

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INITIAL	INDEX	CITATION
	D81	Buchsbaum D.J. et al. <i>Cancer Res.</i> 52: 637-642, 1992. Improved delivery of radiolabeled anti-B1 monoclonal antibody to Raji lymphoma xenografts by predosing with unlabeled anti-B1 monoclonal antibody.
	D82	Buchsbaum D.J. et al. <i>Cancer Res.</i> 52: 6476-81, 1992. Therapy with unlabeled and ¹³¹ I-labeled pan-B-cell monoclonal antibodies in nude mice bearing Raji Burkitt's lymphoma xenografts.
	D83	Buchsbaum D.J. et al. <i>I.J. Rad. Oncol. Biol. Phys.</i> 18: 1033-41, 1990. A comparison of ¹³¹ I-labeled monoclonal antibody 17-1A treatment to external beam irradiation on the growth of LS174T human colon carcinoma xenografts.
	D84	Buchsbaum D.J. et al. <i>I.J. Rad. Oncol. Biol. Phys.</i> 25(4): 629-38, 1993. Comparison of ¹³¹ I- and ⁹⁰ Y-labeled monoclonal antibody 17-1A for treatment of human colon cancer xenografts.
	D85	Byrd J.C. et al. <i>Blood</i> 92(10 Suppl. 1): 106a, abst. no. 432, Nov. 1998. Rituximab therapy in hematologic malignancy patients with circulating blood tumor cells: association with increased infusion-related side effects and rapid tumor lysis.
	D86	Byrd J.C. et al. <i>J. Clin. Oncol.</i> 19(8): 2153-64, 2001. Rituximab using a thrice weekly dosing schedule in B-cell chronic lymphocytic leukemia and small lymphocytic lymphoma demonstrates clinical activity and acceptable toxicity.
	D87	Caligiuri M.A. <i>Semin. Oncol.</i> 20(6 Suppl 9): 3-10, 1993. Low-dose interleukin-2 therapy: rationale and potential clinical applications.
	D88	Caligiuri M.A. et al. <i>J. Clin. Oncol.</i> 9(12): 2110-19, 1991. Extended continuous infusion low-dose recombinant interleukin-2 in advanced cancer: prolonged immunomodulation without significant toxicity.
	D89	Caligiuri M.A. et al. <i>J. Clin. Invest.</i> 91(1): 123-32, 1993. Selective modulation of human natural killer cells in vivo after prolonged infusion of low dose recombinant interleukin 2.
	D90	Calvert J.E. et al. <i>Semin. Hematol.</i> 21(4): 226-243, 1984. Cellular events in the differentiation of antibody-secreting cells.
	D91	Carrasquillo J.A. et al. <i>J. Nucl. Med.</i> 26: 67, abst. no. 276, 1985. Improved imaging of metastatic melanoma with high dose 9.2.27 In-111 monoclonal antibody.
	D92	Cayeux S. et al. <i>Blood</i> 74(6): 2270-77, 1989. T-cell ontogeny after autologous bone marrow transplantation: failure to synthesize interleukin-2 (IL-2) and lack of CD2- and CD3-mediated proliferation by both CD4- and CD8+ cells even in the presence of exogenous IL-2.
	D93	Chen J.J. et al. <i>J. Immunol.</i> 143(3): 1053-57, 1989. Tumor idiotype vaccines. VI. Synergistic anti-tumor effects with combined "internal image" anti-idiotypes and chemotherapy.

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INITIAL	INDEX	CITATION
	D94	Chinn P. et al. <i>Proc. Ann. Mtg. Am. Assn. Cancer Res.</i> 33: 337, abst. no. 2012, 1992. Production and characterization of radiolabeled anti-CD20 monoclonal antibody: potential application to treatment of B-cell lymphoma.
	D95	Chinn P.C. et al. <i>Int. J. Oncol.</i> 15(5): 1017-25, Nov. 1999. Preclinical evaluation of 90Y-labeled anti-CD20 monoclonal antibody for treatment of non-Hodgkin's lymphoma.
	D96	Chinn P.C. et al. <i>Proc. Ann. Mtg. Am. Assn. Cancer Res.</i> 40: 574, abst. no. 3786, 1999. A ⁹⁰ Y-labeled anti-CD20 monoclonal antibody conjugated to MX-DTPA, a high-affinity chelator for yttrium.
	D97	Chomczynski P. et al. <i>Anal. Biochem.</i> 162: 156-59, 1987. Single-step method of RNA isolation by acid guanidinium thiocyanate-phenol-chloroform extraction.
	D98	Clark E.A. et al. <i>J. Cell. Biochem.</i> (Suppl. 9A): 63, 1985. Anti-Bp35 antibody induces human B cell proliferation: implications for <i>in vivo</i> immunotherapy.
	D99	Clark E.A. et al. <i>Proc. Natl. Acad. Sci. USA</i> 82(6): 1766-70, 1985. Role of the Bp35 cell surface polypeptide in human B-cell activation.
	D100	Classon B.J. et al. <i>J. Exp. Med.</i> 169(4): 1497-1502, 1989. The primary structure of the human leukocyte antigen CD37, a species homologue of the rat MRC OC-44 antigen.
	D101	Cogliatti S.B. et al. <i>Sw. Med. Weekly</i> 192: 607-17, 2002. Who is <i>WHO</i> and what was <i>REAL</i> ?
	D102	Cohen Y. et al. <i>Leuk. Lymphoma</i> 43(7): 1485-87, 2002. Large B-cell lymphoma manifesting as an invasive cardiac mass: sustained local remission after combination of methotrexate and rituximab.
	D103	Coiffier B. et al. <i>Blood</i> 92(6): 1927-32, 1998. Rituximab (anti-CD20 monoclonal antibody) for the treatment of patients with relapsing or refractory aggressive lymphoma: a multicenter phase II study.
	D104	Coiffier B. et al. <i>N. Engl. J. Med.</i> 346(4): 235-42, 2002. CHOP chemotherapy plus rituximab compared with CHOP alone in elderly patients with diffuse large-B-cell lymphoma.
	D105	Coleman M. et al. <i>Blood</i> 102(11 pt. 1): 29a, abst. no. 29, 2003. The BEXXAR® therapeutic regimen (tositumomab and Iodine I-131 tositumomab) produced durable complete remissions in heavily pretreated patients with non-Hodgkin's lymphoma (NHL), rituximab-relapsed/refractory disease, and rituximab-naïve disease.
	D106	Colombat P. et al. <i>Blood</i> 97: 101-06, 2001. Rituximab (anti-CD20 monoclonal antibody) as single first-line therapy for patients with follicular lymphoma with a low tumor burden: clinical and molecular evaluation.
	D107	Cope. <i>Oncology</i> 8(4): 100, 1994. Antibody shows promise in treating B-cell lymphoma.

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INITIAL	INDEX	CITATION
	D108	Curti B.D. <i>Crit. Rev. Oncol. Hematol.</i> 14(1): 29-39, Feb. 1993. Physical barriers to drug delivery in tumors.
	D109	Czuczman M. et al. <i>Blood</i> 94(10 Suppl. 1): 99a, abst. no. 432, 1999. Rituximab/CHOP chemioimmunotherapy in patients (PTS) with low grade lymphoma (LG/F NHL): progression free survival (PFS) after three years (median) follow-up.
	D110	Czuczman M.S. et al. <i>J. Clin. Oncol.</i> 17(1): 268-76, Jan. 1999. Treatment of patients with low-grade B-cell lymphoma with the combination of chimeric anti-CD20 monoclonal antibody and CHOP chemotherapy.
	D111	Davis T. et al. <i>Blood</i> 90(10 Suppl. 1): 509a, abst. no. 2269 (Nov. 1997). Retreatments with RITUXAN™ (Rituximab, Idec-C2B8) have significant efficacy, do not cause HAMA, and are a viable minimally toxic alternative in relapsed or refractory non-Hodgkin's lymphoma (NHL).
	D112	Davis T. et al. <i>Proc. Ann. Mtg. ASCO</i> 17: abst. no. 39 (May 1998). Combination immunotherapy of low grade or follicular (LG/F) non-Hodgkin's lymphoma (NHL) with rituximab and alpha interferon: interim analysis.
	D113	Davis T.A. et al. <i>Blood</i> 86(10 Suppl. 1): 237a, abst. no. 1080, 1995. ⁹⁰ Yttrium labeled anti-CD20 therapy for recurrent B cell lymphoma.
	D114	Davis T.A. et al. <i>Blood</i> 92(10 Suppl. 1): 414a, abst. no. 1710, Nov. 1998. Rituximab: phase II (PII) retreatment (ReRx) study in patients (PTS) with low grade or follicular (LG/F) NHL.
	D115	Davis T.A. et al. <i>Blood</i> 92(10 Suppl. 1): 414a, abst. no. 1711, Nov. 1998. Rituximab: first report of a phase II (PII) trial in NHL patients (PTS) with bulky disease.
	D116	Davis T.A. et al. <i>Clin. Cancer Res.</i> 5(3): 611-15, 1999. Therapy of B-cell lymphoma with anti-CD20 antibodies can result in the loss of CD20 antigen expression.
	D117	Davis T.A. et al. <i>J. Clin. Oncol.</i> 17(6): 1851-57, 1999. Single-agent monoclonal antibody efficacy in bulky non-Hodgkin's lymphoma: results of a phase II trial of rituximab.
	D118	Davis T.A. et al. <i>Proc. Ann. Mtg. Amer. Assn. Cancer Res.</i> 39: 435, abst. no. 2964, 1998. Therapy of B cell lymphoma with anti-CD20 can result in relapse with loss of CD20 expression.
	D119	Demidem A. et al. <i>Cancer Biother. Radiopharm.</i> 12(3): 177-86, 1997. Chimeric anti-CD20 (IDEC-C2B8) monoclonal antibody sensitizes a B cell lymphoma cell line to cell killing by cytotoxic drugs.
	D120	DeNardo G.L. et al. <i>Cancer Res.</i> 50(3 Suppl.): 1014s-1016s, 1990. Fractionated radioimmunotherapy of B-cell malignancies with ¹³¹ I-Lym-1.

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INITIAL	INDEX	CITATION
	D121	DeNardo G.L. et al. <i>I.J. Rad. Oncol. Biol. Phys.</i> 11(2): 335-48, 1985. Requirements for a treatment plan in system for radioimmunotherapy.
	D122	DeNardo S.J. et al. <i>Antibody Immunoconj. Radiopharm.</i> 1(1): 17-33, 1988. Pilot studies of radioimmunotherapy of B cell lymphoma and leukemia using I-131 Lym-1 monoclonal antibody.
	D123	DeNardo S.J. et al. <i>Cancer</i> 73(3 Suppl.): 1023-32, 1994. The biologic window for chimeric L6 radioimmunotherapy.
	D124	Di Gaetano N. et al. <i>Br. J. Haematol.</i> 114(4): 800-09, 2001. Synergism between fludarabine and rituximab revealed in a follicular lymphoma cell line resistant to the cytotoxic activity of either drug alone.
	D125	Dickson S. <i>Gen. Engr. News</i> 5(3): 1, March 1985. Scientists produce chimeric monoclonal Abs.
	D126	Dillman R.O. <i>J. Clin. Oncol.</i> 12(7): 1497-1515, 1994. Antibodies as cytotoxic therapy.
	D127	Eary J.F. et al. <i>J. Nuc. Med.</i> 31(8): 1257-68, 1990. Imaging and treatment of B-cell lymphoma.
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EXAMINER / Alana M. Harris/	DATE CONSIDERED April 11, 2008
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